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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,124	03/15/2001	Robert Jason Potter	0942.5030001/RWE	4601
26111	7590	02/05/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			STRZELECKA, TERESA E	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 02/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application N .

09/808,124

Applicant(s)

POTTER ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 02 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 02 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 91-101, 103, 107 and 110-120.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

TS

1/28/04

JEFFREY FREDMAN
PRIMARY EXAMINER

Continuation of 2. NOTE: Applicants' arguments regarding the rejection of claims 11-22 and 63-120 under 35 U.S.C. 112, first paragraph written description, have been considered but were not found to be persuasive. Applicants argue that the claim interpretation which encompasses 684 molecules is unreasonable, since it would include every protein 684 amino acids in length (page 12, last paragraph; page 13, first two paragraphs). However, this is not the case. Since M-MLV reverse transcriptase (RT) has 684 residues, mutating only one of them at a time would produce 684 molecules, mutating two of them would produce 467,856 molecules, etc. All of such molecules would be mutants of M-MLV RT. Applicants described ten such molecules, which is hardly representative even of a genus in which only two residues of M-MLV RT have been mutated. Moreover, as argued by Applicants on page 14, first paragraph, "mutant forms of M-MLV reverse transcriptase are still considered to be M-MLV reverse transcriptases". Therefore, providing only ten species out of possible hundreds of thousands or even millions of mutated M-MLV reverse transcriptases does not fulfill the requirement for providing a representative number to define a genus of all possible M-MLV reverse transcriptases.

Applicants further argue that providing a deposit of biological material in the form of the plasmid pRT601 satisfies written description requirement. However, Applicants do not claim that specific plasmid.

Considering Applicants arguments that structural requirements exist for the function of being a reverse transcriptase, as supported by the paper of Johnson et al., what this paper shows is that some residues are conserved between reverse transcriptases from different virus species. Applicants argue that the C-terminal 150 residues are conserved, as are 250 residues of the N-terminus. However, analysis of Figures 1 and 2 of this references shows that out of the 158 C-terminal residues of M-MLV, only 46 are identical to E. coli ribonuclease H, which isn't even a reverse transcriptase (Fig. 1), and alignment of ribonuclease domains of several reverse transcriptases in Fig. 2 shows that only 10 residues are conserved among the RTs. In Fig. 3, alignment of 251 amino acids from the N-terminus of M-MLV RT with other RTs is shown. Again, 28 residues are conserved among the RTs. Therefore, out of 684 residues of M-MLV RT, 38 might be known by virtue of being conserved in all RTs known before 1986. This still leaves 646 unaccounted for and not described.

Finally, Applicants argue that the tertiary structures of reverse transcriptases are known. However, with only 38 residues conserved among them, the tertiary structure of a reverse transcriptase in which the remaining 646 residues are mutated would most likely be very different from the known structures. The rejection is therefore maintained.

Continuation of 3. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112, first paragraph, written description, for claims 11-22, 63-90, 102, 104-106, 108, 109 (claims cancelled); 35 U.S.C. 112, first paragraph, enablement, for claims 11-22 and 63-120 (claim 11-22, 63-90, 102, 104-106, 108 and 109 were cancelled); 35 U.S.C. 102(a) for claims 71, 82, 91 and 102 (claims 71, 82 and 102 cancelled, claim 91 amended).